

REMARKS

Claims 82 and 87-92 have been canceled. Canceled claims 87, 88, 89 and 90 have been re-written as new claims 95, 96, 97 and 98, respectively. Thus, claims 81, 83-86 and 93-98 are pending.

The Examiner rejected claims 81-86 and 91-94 under 35 U.S.C. § 112, first paragraph, as not enabled. Specifically, the Examiner argues that the specification does not adequately teach a homogenous preparation of any recombinant soluble FcγRIIb receptor, or a pharmaceutical composition comprising any recombinant soluble FcγRIIb receptor. The Examiner does indicate, however, that a preparation of recombinant soluble FcγRIIb receptor containing the amino acid sequence of SEQ ID NO: 3 is enabled.

While Applicants traverse this rejection and maintain that adequate structural and functional characteristics of the receptors are recited, Applicants have amended claim 81 to recite a recombinant soluble FcγRIIb receptor, wherein the receptor contains the amino acid sequence of SEQ ID NO: 3. This amendment is made only to speed up prosecution of this application, so that claims may proceed to allowance. Applicants reserve the right to file subsequent applications to cover the canceled subject matter of the instant application.

The Examiner also maintains that the specification does not teach that the claimed pharmaceutical compositions can be used to effectively treat autoimmune diseases, allergies or tumor diseases including AIDS, rheumatoid arthritis or multiple myeloma. The Examiner points to an absence of animal models and working examples, combined with lack of predictability in the art, to support the argument that an undue amount of experimentation would be required to

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practice the claimed pharmaceutical composition.

Applicants attach a declaration made by co-inventor Dr. Uwe Jacob to prove the pharmaceutical efficacy of the claimed FcγRIIb receptor. The data contained therein proves the efficacy of FcγRIIb in animal models. In light of the declaration, this rejection should be withdrawn.

The Examiner also rejected claims 81, 83, 84, 85, 86, 93 and 94 under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in a way so as to reasonably convey that the inventors had possession of the claimed invention at the time the application was filed. Since the Examiner has indicated that the Applicants are in possession of a homogenous preparation of recombinant soluble FcγRIIb receptor, wherein the receptor contains the amino acid sequence of SEQ ID NO: 3, Applicants' current amendment renders this rejection moot. Therefore, the rejection should be withdrawn.

Claims 81, 83-86, 93 and 94 were further rejected under 35 U.S.C. § 102(e) as being anticipated by Gastinel, et al., U.S. Patent No. 5,623,053. While the '053 patent teaches a general soluble recombinant Fc-receptor that lacks a transmembrane domain, signal peptide and glycosylation, this reference does not disclose a FcγRIIb receptor, wherein the receptor contains the amino acid sequence of SEQ ID NO: 3. Applicants note that claim 81 has been amended to recite that the claimed FcγRIIb receptor contains the amino acid sequence of SEQ ID NO: 3. Applicants further note that canceled claim 82, which recited this receptor, was not included in this rejection. Therefore, in light of Applicants' present amendment, the rejection based on the '053 patent should be withdrawn.

The Examiner also rejected claims 81, 83-86, 93 and 94 under 35 U.S.C. § 102(e) as being anticipated by Hogarth, et al., U.S. Patent No. 6,675,105. The Examiner argues that the '105 patent teaches a pharmaceutical composition comprising a recombinant soluble FcγRIIb receptor characterized by the absence of a transmembrane domain and signal peptide. The Examiner also states that the '105 patent teaches the production of receptors in prokaryotes, hence the receptors could lack glycosylation. The Examiner further notes that SEQ ID NO: 6 of the '105 patent is identical to the claimed SEQ ID NO: 3.

The '105 patent, however, teaches the use of FcγRIIa receptors (see column 14, lines 15-17), whereas the present invention discloses FcγRIIb receptors. These receptor types can be distinguished from one another by their immunological characteristics. The two receptor types possess different binding properties compared to the human and mouse IgG subclasses (Vandewinkel and Kappel, 1993) and a different affinity over human IgGs (Sondermann et al., 1998) (See specification, page 3, lines 15-19). Furthermore, SEQ ID NO: 3 of the instant application comprises an additional five N-terminal and ten C-terminal amino acids compared to SEQ ID NO: 6 of the '105 patent. Hence, SEQ ID NO: 3 cannot be anticipated by the '105 patent. In fact, the Examiner acknowledges this point, since canceled claim 82 (which recited SEQ ID NO: 3) was not included in this rejection. Since claim 81 has been amended to recite that the claimed FcγRIIb receptor contains the amino acid sequence of SEQ ID NO: 3, this rejection should also be withdrawn.

All rejections have been addressed and should be withdrawn. Applicants respectfully request allowance of this application.

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A petition for a two month extension of time and a check for the required fee accompanies this amendment. If any additional fees are due, please charge Deposit Account No. 50-0624, under Order No. NY-HUBR 1189-US, from which the undersigned is authorized to draw.

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Respectfully submitted,

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